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RELIABILITY OF THE EPWORTH SLEEPINESS SCALE AND THE BERLIN QUESTIONNAIRE FOR SCREENING OBSTRUCTIVE SLEEP APNEA SYNDROME IN THE CONTEXT OF THE EXAMINATION OF CANDIDATES FOR DRIVERS

WIARYGODNOŚĆ SKALI SENNOŚCI EPWORTH I KWESTIONARIUSZA BERLIŃSKIEGO W DIAGNOSTYCE PRZESIEWOWEJ ZESPOŁU OBTURACYJNEGO BEZDECHU SENNEGO W KONTEKŚCIE BADAŃ KANDYDATÓW NA KIEROWCÓW

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ABSTRACT

Background: The aim of the study has been to assess the usefulness of the Epworth Sleepiness Scale (ESS) and the Berlin Questionnaire (BQ) for obstructive sleep apnea syndrome (OSAS) screening. The capacity of both tests to discriminate between healthy individuals or with mild OSAS (apnea-hypopnea index (AHI) < 15/h) vs. patients with moderate or severe OSAS (AHI ≥ 15/h) was evaluated. **Material and Methods:** The study encompassed 223 patients with a suspicion of the OSAS. The ESS and BQ were completed by patients unassisted. Screening polysomnography was performed using the Porti SleepDoc. The OSAS was diagnosed when AHI ≥ 15/h or AHI ≥ 5/h with simultaneous occurrence of clinical symptoms. **Results:** The ESS score was found to be significantly higher in the study group compared to the control group (8.9±5.9 vs. 11.6±5.2 pt, $p < 0.0001$). Otherwise, there were no significant inter-group differences in the percentage of high-risk individuals according to the BQ (83.7% vs. 92.3%, $p > 0.05$). Sensitivity of the ESS and BQ was 53.2% and 93.1%, respectively while specificity was 58.8% and 16.2%, respectively. Poor correlation between the ESS score and AHI and apnea index were noticed ($r = 0.22$, $p = 0.001$ and $r = 0.24$, $p < 0.001$, respectively). **Conclusions:** Considering its low sensitivity, the ESS should not be used as a screening test for the OSAS diagnosis amongst candidates for drivers. The BQ is characterised by high sensitivity for the OSAS diagnosis with AHI ≥ 15/h, however, due to low specificity, the questionnaire may increase the number of healthy individuals referred for needless diagnostic procedures. Med Pr 2016;67(6):721–728

Key words: occupational medicine, reliability, drivers' examinations, obstructive sleep apnea syndrome, questionnaires, polysomnography

STRESZCZENIE

Wstęp: Celem pracy była ocena przydatności Skali Senności Epworth (SSE) i Kwestionariusza Berlińskiego (KB) w diagnostyce przesiewowej zespołu obturacyjnego bezdechu sennego (obstructive sleep apnea syndrome – OSAS). Oceniono przydatność obu testów do różnicowania osób zdrowych od osób z łagodnym OSAS (wskaźnik bezdechu i spłyceń oddechu (apnea-hypopnea index – AHI) < 15/godz.) i pacjentów z umiarkowanym lub ciężkim OSAS (AHI ≥ 15/godz.). **Materiał i metody:** Do badania włączono 223 pacjentów z podejrzeniem zaburzeń oddychania w czasie snu, którzy wypełnili SSE i KB. Uproszczoną polisomnografię wykonano z wykorzystaniem urządzeń Porti SleepDoc. W przypadku stwierdzenia AHI ≥ 15/godz. lub AHI ≥ 5/godz. i jednoczesnego występowania objawów klinicznych rozpoznawano OSAS. **Wyniki:** Wynik SSE był istotnie wyższy w grupie badanej niż w grupie porównawczej (8,9±5,9 vs 11,6±5,2 pkt, $p < 0,0001$), natomiast odsetek osób z wysokim ryzykiem OSAS według KB nie różnił się istotnie w obu grupach (83,7% vs 92,3%, $p > 0,05$). Czułość SSE wyniosła 53,2%, a KB – 93,1%, natomiast swoistość SSE – 58,8%, a KB – 16,2%. Odnotowano słabą korelację między wynikiem SSE a AHI i wskaźnikiem bezdechów (odpowiednio: $r = 0,22$, $p = 0,001$ vs $r = 0,24$, $p < 0,001$). **Wnioski:** Ze względu na niską czułość SSE nie powinna być stosowana jako

samodzielny test przesiewowy w diagnostyce OSAS u kandydatów na kierowców. Natomiast KB, mimo że cechuje się dużą czułością w rozpoznawaniu umiarkowanego lub ciężkiego OSAS ($AHI \geq 15/\text{godz.}$), z powodu bardzo niskiej swoistości może przyczynić się do kierowania osób zdrowych na zbędną diagnostykę. *Med. Pr.* 2016;67(6):721–728

Słowa kluczowe: medycyna pracy, wiarygodność, badania kierowców, zespół obturacyjnego bezdechu sennego, badania ankietowe, polisomnografia

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INTRODUCTION

Obstructive sleep apnea syndrome (OSAS) is the most common type of sleep-related breathing disorders (SRBD). Population-based studies demonstrate a prevalence of the OSAS to be approximately 3–7% for men and 2–5% for women [1,2]. Obstructive sleep apnea syndrome is characterized by repeated episodes of complete or partial upper airway obstruction during sleep resulting in cyclic periods of hypoxaemia and hypercapnia, which lead to adverse neurohumoral and clinical sequels.

The typical symptoms of the OSAS include snoring, apnoas or hypopnoas, nycturia, arousals during sleep, morning fatigue and headaches, excessive daytime sleepiness, and concentration disorders. Obstructive sleep apnea syndrome is not only associated with the worse quality of life but also with an increased risk of cardiovascular diseases. The major risk factors of the OSAS are obesity and upper airway and craniofacial anomalies. To determine the severity of the OSAS the apnoea-hypopnoea index (AHI) is used, which is the number of apneas and hypopneas per hour. The obstructive sleep apnea syndrome is diagnosed when $AHI \geq 5/\text{h}$ with simultaneous occurrence of typical clinical symptoms or when $AHI \geq 15/\text{h}$. Three degrees of the OSAS severity were distinguished: mild with $AHI \geq 5/\text{h}$ and $< 15/\text{h}$ accompanied by typical clinical symptoms, moderate with $AHI \geq 15/\text{h}$ and $< 30/\text{h}$, and severe with $AHI \geq 30/\text{h}$ [3].

The sleep-related breathing disorder remains underdiagnosed and insufficiently treated in the group of professional drivers [4]. Persistent daytime sleepiness and falling asleep behind the wheel are considered the leading causes of road accidents caused by drivers [4]. Studies carried out in the United States demonstrate that excessive sleepiness of drivers was responsible for 36% of traffic collisions with fatalities and for 42–54% of all road traffic accidents [5]. Tregear et al. published meta-analysis of 18 studies regarding road traffic accidents amongst patients with the OSAS. The risk of road ac-

cident in these patients was 1.21–4.89 times higher than that in healthy individuals. The factors affecting the increased risk of road accidents in patients with the OSAS included the body mass index (BMI), AHI and nocturnal hypoxaemia [6].

According to the data of the Police Headquarters of 2014, 34 970 road traffic accidents were reported in Poland, drivers were responsible for 82.2% of them. Falling asleep or fatigue of the driver was found the cause of accident in 1.9% of cases [7]. However, the data presented is likely to be underestimated, as compared to the statistics from other countries. Minarowski et al. demonstrated that excessive daytime sleepiness was present in almost 5% of professional bus drivers [8].

Considering the above facts, the European Committee had accepted the changes in the European Union Directive of 2006/126/EC [9], which the members were obliged to introduce since December 31, 2015. In Poland, the Directive of the Minister of Health was issued on December 23, 2015 [10], which changes the directive regarding medical examinations of candidates for drivers and drivers. According to the new regulations, candidates for drivers and drivers suspected of moderate or severe OSAS (i.e., $AHI \geq 15/\text{h}$) should be referred for specialist medical tests. The golden diagnostic standard is polysomnography. Due to limited availability of specialist laboratories, long waiting lists and costs, screening tests should be searched for that would enable simple and inexpensive selection of patients with the potentially highest risk of OSAS.

The aim of the present study has been to assess the usefulness of 2 questionnaires: the Epworth Sleepiness Scale (ESS) and the Berlin Questionnaire (BQ) for OSAS screening [11,12]. Taking into account clinical issues and valid legal regulations regarding candidates for drivers, the capacity of both tests to discriminate between healthy individuals and patients with mild OSAS ($AHI < 15/\text{h}$) vs. patients with moderate and severe OSAS ($AHI \geq 15/\text{h}$) was evaluated.

MATERIAL AND METHODS

Patients

The study encompassed 223 patients with a suspicion of sleep-related breathing disorders, who were diagnosed at the sleep lab affiliated with the clinic of internal diseases of university hospital between 2012–2014.

The Epworth Sleepiness Scale (ESS) and Berlin Questionnaire (BQ) were completed by patients unassisted following short instructions provided by the physician. The ESS score ≥ 11 was considered suggestive of excessive daytime sleepiness. The BQ results were categorized into low and high risk of the OSAS. Additionally, all the patients underwent physical examinations, basic laboratory tests and screening polysomnography (PSG).

Polysomnography

Screening overnight PSG was performed without the adaptive night using the Porti SleepDoc 6/8 (Dr. Fenyes und Gut Deutschland GmbH, Germany). Air flow, snoring, body position, and pulsometric recordings were monitored. The following PSG parameters were recorded: the apnea-hypopnea index (AHI) expressing the number of apnea and hypopnea episodes per 1 h of examination, the apnea index (AI) and hypopnea index (HI), reflecting the number of apnea and hypopnea episodes per 1 h, respectively. The following nocturnal oximetry parameters were analyzed: mean and minimum saturation (peripheral oxygen saturation – SpO₂); and cumulative time percentage with SpO₂ < 90% (t90 known also as time of hypoxia). Obstructive sleep apnea syndrome was diagnosed according to the recommendations of the American Academy of Sleep Medicine when AHI ≥ 15 /h or AHI ≥ 5 /h with simultaneous occurrence of typical clinical symptoms [3].

Patients with PSG-based diagnoses of the moderate and severe OSAS (AHI ≥ 15 /h) were included in the study group (N = 128) whereas those with unconfirmed or the mild OSAS (AHI ≥ 5 /h and < 15/h) constituted the reference group (N = 95).

Statistical analysis

Statistica 12 PL software was used for statistical analysis purposes. Continuous data was expressed as mean (M) \pm standard deviation (SD). Normal distribution of continuous variables was checked using the Shapiro-Wilk test. Significance of differences for 2 independent samples was assessed using the Student's t-test or the Mann-Whitney U test, when appropriate. Inter-group differences for categorical variables were analyzed with the Chi² test. Correlations between variables were analyzed with the Pearson's correlation coefficient or its non-parametric equivalent – the Spearman's rank correlation coefficient for non-normal distribution.

To assess diagnostic reliability of the ESS and BQ, sensitivity, specificity, accuracy as well as positive and negative likelihood ratio were calculated.

For all tests $p < 0.05$ was considered as statistically significant.

RESULTS

The study group (AHI ≥ 15 /h) included 128 patients, predominantly men, with moderate or severe OSAS aged 54.6 ± 11.1 years (Table 1). The reference group (i.e., individuals with AHI ≤ 15 /h) consisted of 95 patients with the mild OSAS or normal PSG recordings, also predominantly men, whose age was 49.5 ± 13.8 years old.

The Table 1 presents additional clinical characteristics and the PSG findings in both groups. It is worth stressing that the ESS score was found to be significantly

Table 1. Characteristics of the study group of patients with a suspicion of sleep-related breathing disorders
Tabela 1. Charakterystyka badanej grupy pacjentów z podejrzeniem zaburzeń oddychania w czasie snu

Characteristics Charakterystyka	Respondents Badani (N = 223)		P
	AHI < 15/h AHI < 15/godz. (N = 95)	AHI ≥ 15 /h AHI ≥ 15 /godz. (N = 128)	
Age [years] / Wiek [w latach] (M \pm SD)	49.5 \pm 13.8	54.6 \pm 11.1	< 0.01
Sex / Płeć [%]			< 0.0001
men / mężczyźni	64.0	85.0	
women / kobiety	36.0	15.0	

Table 1. Characteristics of the study group of patients with a suspicion of sleep-related breathing disorders – cont.
Tabela 1. Charakterystyka badanej grupy pacjentów z podejrzeniem zaburzeń oddychania w czasie snu – cd.

Characteristics Charakterystyka	Respondents Badani (N = 223)		P
	AHI < 15/h AHI < 15/godz. (N = 95)	AHI ≥ 15/h AHI ≥ 15/godz. (N = 128)	
Body mass index / Wskaźnik masy ciała (BMI) [kg/m ²] (M±SD)	30.4±4.9	33.5±5.2	< 0.0001
Arterial hypertension / Nadciśnienie tętnicze [%]	70.5	78.9	n.s.
Type 2 diabetes mellitus / Cukrzyca typu 2 [%]	20.1	33.3	n.s.
Ischemic heart disease / Choroba niedokrwienna serca [%]	15.2	18.2	n.s.
Chronic obstructive pulmonary disease / Przewlekła obturacyjna choroba płuc [%]	6.2	8.3	n.s.
Cigarette smoking / Palenie papierosów [%]	11.2	15.8	n.s.
Alcohol dependence / Uzależnienie od alkoholu [%]	1.1	1.5	n.s.
Berlin Questionnaire / Kwestionariusz Berliński [%]	83.7	92.3	n.s.
Epworth Sleepiness Scale [pt] / Skala Senności Epworth [pkt] (M±SD)	8.9±5.9	11.6±5.2	< 0.0001
AHI [xh ⁻¹] / AHI [xgodz. ⁻¹] (M±SD)	6.5±4.4	43.5±20.6	< 0.0001
Mean nocturnal saturation / Średnia nocna saturacja [%] (M±SD)	92.1±1.8	89.5±3.7	< 0.0001
Minimum nocturnal saturation / Minimalna nocna saturacja [%] (M±SD)	83.3±5.5	69.9±12.6	< 0.0001
Time of hypoxia / Czas hipoksji (t90) [%] (M±SD)	4.9±12.9	24.9±23.9	< 0.0001

AHI – apnea-hypopnea index / wskaźnik bezdechów i słyceń oddechów.

M – mean / średnia, SD – standard deviation / odchylenie standardowe.

n.s. – statistically not significant / nieistotne statystycznie.

Table 2. Diagnostic reliability of the Epworth Sleepiness Scale (ESS) and Berlin Questionnaire (BQ) for diagnosis of moderate or severe obstructive sleep apnea syndrome (OSAS) (i.e., AHI ≥ 15/h)

Tabela 2. Wiarygodność diagnostyczna Skali Senności Epworth (SSE) i Kwestionariusza Berlińskiego (KB) w rozpoznawaniu umiarkowanego lub ciężkiego zespołu obturacyjnego bezdechu sennego (OSAS) (tj. AHI ≥ 15/godz.)

Diagnostic reliability parameter Parametr wiarygodności diagnostycznej	ESS SSE	BQ KB
Sensitivity / Czulość [%]	53.20	93.10
Specificity / Swoistość [%]	58.80	16.20
Positive likelihood ratio / Dodatni wskaźnik wiarygodności	1.29	1.11
Negative likelihood ratio / Ujemny wskaźnik wiarygodności	0.79	0.42
Accuracy / Dokładność [%]	55.60	56.70

AHI – apnea-hypopnea index / wskaźnik bezdechów i słyceń oddechów.

higher in the study group compared to the group of patients with AHI < 15/h (8.9±5.9 pt vs. 11.6±5.2 pt, $p < 0.0001$). Otherwise, there were no significant inter-group differences in the percentage of high-risk individuals according to the BQ (83.7% vs. 92.3%, $p > 0.05$).

Detailed results of analysis of the ESS and BQ diagnostic reliability are listed in the Table 2.

The Epworth Sleepiness Scale was characterized by low sensitivity (53.2%) and specificity (58.8%) while the BQ has relatively good sensitivity (93.1%) but very poor specificity (16.2%). Accuracy of both the ESS and BQ was poor (55.6% and 56.7%, respectively).

Moreover, the Table 3 presents correlations between ESS results and PSG parameters describing the severity of OSAS.

Significant but weak correlations were noted between the ESS score and AHI and AI ($r = 0.22$, $p = 0.001$ and $r = 0.24$, $p < 0.001$, respectively). Correlations between the ESS and desaturation indices were very weak (for minimal saturation $r = -0.18$, $p = 0.01$, for mean nocturnal saturation $r = -0.16$, $p = 0.02$ and for time of hypoxia $r = 0.18$, $p = 0.01$).

The Figure 1 presents a correlation between the AHI and ESS score.

Predictive usefulness of the ESS for diagnosis of the OSAS with $AHI \geq 15/h$ is presented using a ROC curve in the Figure 2. The suggested cut-off value

was 11 pt. The area under the curve was 0.623 (95% confidence interval (CI): 0.547–0.699) which indicates the poor predictive value of the ESS score.

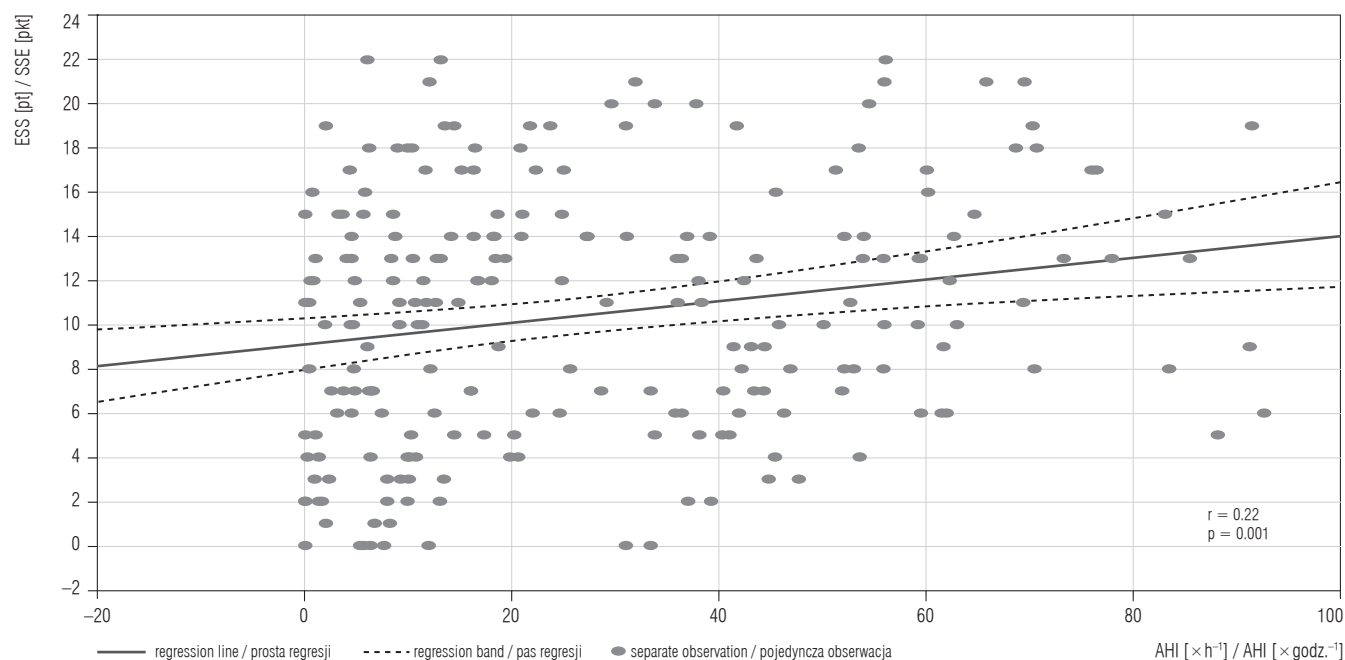
DISCUSSION

A good screening test should be characterized by high sensitivity (few false negative results) and high specificity (few false positive results); it should be simple, inexpensive and non-invasive. Such a test reduces the risk of overlooking the affected and does not expose healthy individuals to medical procedures.

Table 3. Severity of the sleepiness according to the Epworth Sleepiness Scale (ESS) and polysomnographic parameters
Tabela 3. Nasilenie senności według Skali Senności Epworth (SSE) a parametry polisomnograficzne

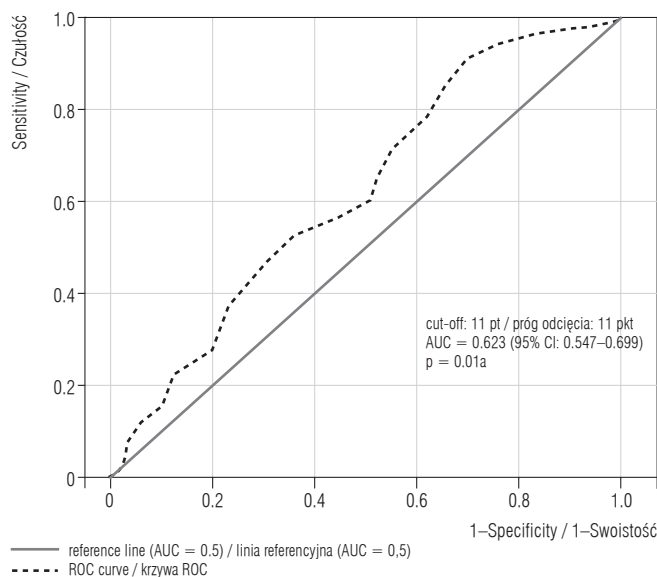
Polysomnographic parameter Parametr polisomnograficzny	r_{ESS} r_{SSE}	p
Apnea-hypopnea index / Wskaźnik bezdechów i sypień oddechów	0.22	0.001
Apnea index / Wskaźnik bezdechów	0.24	< 0.001
Hypopnea index / Wskaźnik sypień oddechów	0.06	n.s.
Mean nocturnal saturation / Średnia nocna saturacja	-0.16	0.02
Minimum nocturnal saturation / Minimalna nocna saturacja	-0.18	0.01
Time of hypoxia / Czas hipoksji (t90)	0.18	0.01

r – correlation coefficient / współczynnik korelacji.



r – correlation coefficient / współczynnik korelacji.

Fig. 1. Apnea-hypopnea index (AHI) and Epworth Sleepiness Scale (ESS) score
Ryc. 1. Wskaźnik bezdechów i sypień oddychania (AHI) a wynik Skali Senności Epworth (SSE)



AHI – apnea-hypopnea index / wskaźnik bezdechów i splotów oddechów,
 AUC – area under the curve / pole pod krzywą, CI – confidence interval / przedział
 ufności.

Fig. 2. Epworth Sleepiness Scale (ESS) score as a classifier of moderate or severe obstructive sleep apnea syndrome (OSAS) (i.e., AHI \geq 15/h)

Ryc. 2. Punktacja Skali Senności Epworth (SSE) jako klasyfikator umiarkowanego lub ciężkiego zespołu obturacyjnego bezdechu sennego (OSAS) (tj. AHI \geq 15/godz.).

In this study, the ESS was found to show low sensitivity (53.2%) and specificity (58.8%) for diagnosis of moderate and severe OSAS (AHI \geq 15/h). The similar results were reported by Hesselbacher et al. for the American population; the ESS sensitivity for the diagnosis of the OSAS was 54% while its specificity 57% [13]. According to Hobson et al., the ESS sensitivity increased to 70% when items regarding driving a vehicle were excluded [14].

Comparison between self-administered and physician-administered questionnaires was not the aim of this study. Studies published so far are inconsistent in this matter. It was demonstrated that the results of the ESS questionnaires carried out by physicians differed from those filled unaided (8.3 ± 5.8 vs. 9.4 ± 5.8 , $p < 0.0001$) [15]. On the other hand, Damiani et al. showed that the results of the physician-administered ESS were higher than a conventional, self-administered questionnaire (12.09 ± 4.1 vs. 10.37 ± 5.49 , $p = 0.01$) and were stronger correlated apnea-hypopnea index assessed with portable device [16].

While completing the questionnaire, the patient provides information he/she believes is true, which is not validated in any way (e.g., by family members). Some patients consider excessive sleepiness as “normal” con-

dition (clinical experience show that many patients with OSAS admit that their earlier functioning and activity was abnormal once continuous positive airway pressure treatment has been started); some believe that even slight weakness indicates some disease. Moreover, resting, type and mode of work, other diseases inducing similar symptoms (e.g., chronic anaemia, hypothyroidism) are not taken into account. The above and many other factors (including lack of nocturnal symptoms assessment) are likely to affect the final ESS results.

Noteworthy, in this study the ESS questionnaires were not completed in the occupational medicine service setting, which eliminates the risk of dissimulation. The findings confirm the opinions of Hesselbacher et al. that the ESS sensitivity is so low that the scale cannot be used as a screening tool when other clinical data is not provided [13].

The Berlin Questionnaire is another, widely available, and easy to use screening method for the diagnosis of the OSAS. The questionnaire may be completed by the patient unassisted (lucid form, easy-to-understand items) or assisted by the medical personnel. Gus et al. have demonstrated that a high risk of the OSAS determined based on the BQ was positively correlated with resistant hypertension [17]. The study performed amongst patients with angina pectoris symptoms has revealed that the BQ is a useful tool to define the need for further diagnosis of obstructive sleep apnea syndrome (OSAS). The test sensitivity was 70% and its specificity 48% [18].

In this study, the BQ was found to be of high sensitivity (93.1%) and low specificity (16.2%) for diagnosis of the moderate and severe OSAS (AHI \geq 15/h). Thus, it may be assumed that its sensitivity is satisfactory (few false negative results). The sensitivity reported by the authors of this questionnaire (Netzer et al. [12]) was 86%, i.e., comparable with the authors of this study's results. However, the BQ specificity in Netzer et al.'s study and this study substantially differs. In the study by Netzer et al., the specificity was 77% while in this study – only 16.2% [12]. Moreover, previous studies also demonstrated low specificity of BQ for diagnosis of the severe or any severity OSAS (17.5% and 11.5%, respectively) [19,20].

Therefore, it should be taken into consideration that the BQ gives many false positive results, which is associated with more frequent referrals for polysomnography, queues in sleep apnoea laboratories and high costs of unjustified diagnostic procedures. In Poland, polysomnographic diagnostics for insured individuals is currently available only during hospitalizations.

It might to be considered to take into account simple anthropometric parameter (i.e., body mass index, neck circumference, upper airway abnormalities) to increase predictive value of questionnaires-based assessment. However, Raman et al. demonstrated that addition of points scored for body mass index and neck circumference made only a minor improvement to the predictive utility of the pediatric screening scale [21]. There is no reliable evidence on the usefulness Mallampati score in screening for OSAS [22].

Portable monitors (class 4 according to American Academy of Sleep Medicine) may be an alternative to full polysomnography in ambulatory settings. Such devices do not have the capacity to record total sleep time and arousals, therefore the results may be underestimated. However, the recent study by Bilgin et al. provides evidence that results of night oximetry are strongly correlated with PSG outcomes [23].

It is worth mentioning the studies on methods for detection of drowsiness while driving a car. There is the ongoing research on mobile devices that can be built into cars and analyze some physiological parameters (e.g., percentage of eyelid closure, blink velocity-based score, average pupil diameter, electroencephalogram (EEG) signal, standard deviation of lateral position and steering wheel reversals) to warn a driver in advance [24–26].

Further research on optimal screening procedures for OSAS for drivers and candidates for drivers is needed.

CONCLUSIONS

1. Considering its low sensitivity and poor correlation with polysomnographic findings, the ESS should not be used as an independent screening test for OSAS diagnosis amongst candidates for drivers.
2. The BQ is characterized by high sensitivity for OSAS diagnosis with AHI \geq 15/h (prevents abandonment of diagnosis in high-risk patients). However, due to low specificity and many false positive results, the questionnaire may increase the number of individuals referred for needless and cost-consuming hospital diagnostic procedures.
3. Both the BQ and ESS may be used for screening yet should be combined with meticulous history taking (with relations of family members, if possible) and physical examinations (including BMI, cervical circumference, basic ear, nose, throat (ENT) examination).

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